

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-6, 9-11 and 19 are pending in the application, with claims 1, 9 and 19 being the independent claims. Claims 7-8 and 12-18 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-6 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite and failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Paper No. 17, page 2. Applicants respectfully traverse the rejection.

The Examiner has stated that the phrase "associating the analyte with a thermostable reporter kinase" in claim 1 is allegedly unclear as to whether a complex is being formed. Paper No. 17, page 3. Applicants respectfully disagree. Claim 1 is definite because it is clear from the existing wording that a complex is formed.

Definiteness of claim language must be reviewed in light of the specification. MPEP § 2173.02 (8th ed., Rev. Feb. 2003). In addition, the test for indefiniteness is whether the scope of the claim is clear to a hypothetical person possessing an ordinary level of skill in the pertinent art. M.P.E.P. § 2171. The specification describes how an analyte can be associated with a thermostable reporter kinase. For example, the reporter adenylate kinase can be coupled to an antibody that binds specifically to the analyte. *See Specification*, page 5, lines 14-15. In addition, the analyte and the thermostable reporter kinase can be associated via a binding agent which is coupled or conjugated to the kinase. *See Specification* page 5, line 24 through page 6, line 4. One skilled in the art would know that when antibodies, proteins, or enzymes are coupled, conjugated, or specifically bound that they necessarily form a complex. Thus, it is clear from the wording in claim 1 that a complex is being formed.

The Examiner has stated that the term "reporter kinase" in claim 1 is unclear. Paper No. 17, page 3. Applicants have amended claim 1 so that the phrase "reporter kinase" now reads as "thermostable reporter kinase." Therefore, this rejection of claim 1 has been rendered moot.

The Examiner has further alleged that claim 1 recites that endogenous kinase is inactivated by heat and it is unclear how heat affects the other reagents. Paper No. 17, page 3. Applicants respectfully disagree. Claim 1 specifies that ADP (which is heat-labile) is added after the heating step. One skilled in the art would recognize that this indicates that at the time the heating step is applied, either no other heat-labile

components are present in the assay or such heat-labile contaminating components are inactivated. Claim 1 is thus clear as to how heat affects the other reagents.

The Examiner also alleges, with respect to claim 1, that it is unclear how the analyte is detected. Paper No. 17, page 3. Applicants respectfully disagree. Claim 1 includes the step of testing for the formation of ATP. It is not necessary to specify how in particular the analyte is detected. The specification describes how the formation of ATP can be used to detect the presence and amount of an analyte. *See e.g. Specification*, page 25, lines 28-32 and page 27, lines 1-9. Thus, claim 1 is definite with respect to how the analyte is detected.

The Examiner has rejected claim 4 as allegedly not being clear with regard to the binding relationship between the reporter adenylate kinase, the analyte, and the antibody. Paper No. 17, page 3. Applicants respectfully disagree. Claim 4 recites a reporter adenylate kinase coupled to a binding agent specific for the analyte. Claim 4 does not recite antibody. Applicants have amended claim 4 to add the phrase "via the binding agent," to clarify the binding relationship between the reporter adenylate kinase, the analyte, and the binding agent.

The Examiner has also rejected claim 4 as allegedly being unclear as to how ADP binds to the reporter adenylate kinase when it is associated with the analyte. Paper No. 17, page 3. The test for indefiniteness is whether the scope of the claims is clear to a hypothetical person possessing an ordinary level of skill in the pertinent art. M.P.E.P. §2171. It is well known to one skilled in the art that adenylate kinase enzymes

bind ADP at their active site. Thus, claim 4 is definite with regard to how ADP binds to the reporter adenylate kinase.

Finally, the Examiner has rejected claim 9 as allegedly being unclear as to how the presence of the detector composition is determined by the addition of a substrate. Paper No. 17, page 3. Applicants respectfully disagree. Applicants have nonetheless amended claim 9 to include the phrase "and measuring a product formed by conversion of said substrate to said product by said thermostable enzyme" in order to make explicit how the presence of the detector composition is determined. Thus, the rejection of claim 9 has been rendered moot.

Based on the above Remarks, Applicants respectfully request that the rejections under 35 U.S.C. § 112, second paragraph be reconsidered and withdrawn.

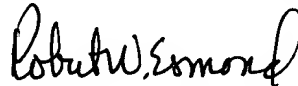
Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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